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--~~36~~. The stimulator as recited in claim ²⁰~~18~~

further including a programmable control store for defining a sequence of electrical events corresponding to at least one mode of operation and associated operating parameters associated with said operation; and

an input/output data channel connected to said control store for transferring data therewith which define the sequence of electrical events to be performed by said at least one mode of operation thereby to affect treating operations particularly suited to the patient.--

¹⁹
--~~37~~. The stimulator as recited in claim ¹⁸~~35~~

wherein said programmable control store defines a defibrillating mode of operation and a set of operating parameters including step wise increased energy levels for said defibrillating pulses, said executing means being responsive to said programmable control store to defibrillate the heart in accordance with the programmed mode of operation and the defined operating parameters associated therewith.--

REMARKS

The Examiner rejects claims 1-5 and 10-14 under 35 U.S.C. §102(b) as being anticipated by Rubin (U.S. Patent 3,857,398). Applicants contend that such a rejection is unwarranted. To support this contention though applicants amend slightly independent claims 1 and 10 to more clearly set out the structural differences thereby to define the claims over the Rubin patent. In particular, applicants recite that the claimed stimulator possesses the capability

of being programmed to operate in a single or multimode of operation which operation corresponds to a determined condition of the heart. A mode of operation is a sequence of electrical events to treat the heart. The claimed invention sets out a method and apparatus for undergoing several different sequences of events, which sequences are uniquely identified with a respective detected heart condition.

In considering the disclosure of Rubin, it is observed that the cardiac defibrillator thereof is not a state device capable of operating in more than one mode of operation, as claimed by applicant's invention. The defibrillator of Rubin merely includes a analyzer/controller circuit 12 which activates either a demand pacer 11 or defibrillator 10 in a predefined single mode of operation. Whether the pacer or defibrillator is activated depends on the signals received from an AND gate 40. More importantly though the Rubin system is not capable of being programmed in a manner for determining which mode, modes and/or sequence of modes of operation the stimulator will undergo. The Rubin system merely detects fibrillation and issues a defibrillating pulse or detects the absence of a natural R-wave and issues a pacing pulse. On the contrary, applicants claimed invention, as more clearly defined, is a stimulator capable of being preprogrammed for undergoing a variety of pacing modes, defibrillating modes, or cardioverting modes of operation. Thus, the claimed invention is more advantageous than that provided by Rubin in that it has greater flexibility for suiting the particular needs of a particular patient. For these reasons, the rejection of independent claims 1 and 10

under 35 U.S.C. §102(b) should be withdrawn. Further, the Examiner should not apply the Rubin reference under §102(b) to the newly added independent claims 27-37 for the same reasons stated herein.

The Examiner rejects claim 6 under 35 U.S.C. §103 as being unpatentable over Rubin in view of Denniston et al asserting that providing two separate processors is an obvious matter of choice. Applicants have, however, carefully reviewed the disclosure of Denniston et al, and have been unable to find "two separate processors" in the Denniston patent disclosure as the Examiner claims to exist. Instead, Denniston discloses and describes "redundant" sensing systems for monitoring two separate and distinct characteristics of the heart. It does not disclose two processors which operate independently of one another. Refer, for example, to column 3, lines 30-35 of the Denniston et al specification, where it is stated that "the cardioverting circuit comprises two basic subsystems; a sensing system and a stimulation system". Thereafter, the specification specifies that the sensing system monitors two dynamic characteristics of the heart, such as an EKG signal and a muscle contraction signal. Nowhere in the Denniston et al patent is there disclosed two separate processors wherein each processor operates independently of one another for performing separate and distinct tasks as provided by claim 6. For this reason, the rejection of claim 6 under 35 U.S.C. §103 should be withdrawn. Also, since claim 6 depends from claim 1, it is argued that claim 6 should be allowable for reasons stated with respect to claim 1.

Claim 7 stands rejected under 35 U.S.C. §103 as being unpatentable over Rubin in view of Buffet. As to this rejection, we advance the arguments made with respect to independent claim 1, from which claim 7 depends.

Claims 8-9, 15-19 and 22-26 stand rejected under 35 U.S.C. §103 as being unpatentable over Rubin in view of Rizk or Auerbach et al stating that use of a forced R-wave detector is obvious. As to these claims, applicant also reiterates those arguments made with respect to independent claims 1, 10, and 18 from which these claims respectively depend so that the question of their novelty turns on a broader aspect of the invention. The Examiner should note that this group of claims has been only slightly amended to more clearly specify what is being accomplished but, in substance, no change thereof has been made, except as to the independent claims from which they depend.

Claim 20 stands rejected under 35 U.S.C. §103 as being unpatentable over Rubin in view of Rizk or Auerbach as applied to claim 18 and further in view of Morowski et al, the Examiner contending that providing an input/output data channel is obvious. Again, applicant reiterates those arguments made with respect to claim 18 from which claim 20 depends to support patentability thereof. Applicant comments though that newly added dependent claims 27-37 more particularly specify the structure of the input/output data channel and that the features so defined clearly distinguish over the cited prior art. In particular, the I/O data channels couples a program control store thus to transfer information which alter the state (e.g., mode) of operation of the

implantable stimulator. This feature is not shown by the cited art.

Claim 21 stands rejected under 35 U.S.C. §103 as being unpatentable over Rubin in view of Rizk or Auerbach et al as applied to claim 18, and further in view of Buffet. The Examiner contends that providing a micro-processor is an obvious matter of choice. Here again, applicants reiterate the arguments made with respect to claim 18, from which claim 21 depends, and further comment that all that is said about Buffet is that the stimulator is controllable via a magnetic relay switch and that, to applicants' knowledge, the system of Buffet does not appear to be programmable in a manner to generate output control signals in dependence on data signals received over an input/output data channel, as now recited in amended claim 21. For this reason and others, the rejection of claim 21 also should be withdrawn.

Further, applicant submits herewith the required extension fee of \$50.00.

In view of the foregoing, it is respectfully requested that the Examiner reconsider the patentability of the claims now present in the case. Favorable and early action is respectfully requested. The Examiner is urged to

telephone the undersigned if it is believed that such action would facilitate the prosecution of this case.

Respectfully submitted,

FLEIT, JACOBSON & COHN

By: Ronald D. Cohn
Ronald D. Cohn
Reg. No. 25,203

2033 M Street, N.W.
Washington, D.C. 20036-3399
(202) 466-8800

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